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10/533,277	11/28/2005	Tadayoshi Mitsuhashi	690107.404USPC	5923	
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			SHAW, AMANDA MARIE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/533 277 MITSUHASHI, TADAYOSHI Office Action Summary Examiner Art Unit AMANDA SHAW 1634 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 26 February 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-19 is/are pending in the application. 4a) Of the above claim(s) 8 and 11-19 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-7, 9-10 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 4/28/2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Minformation Disclosure Statement(s) (PTO/S5/08)

Paper No(s)/Mail Date 11/28/05, 6/7/06, 9/14/06.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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Election/Restrictions

 Applicant's election of Group I (Claims 1-7 and 9-10) in the reply filed on August February 26, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8 and 11-19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claims.

Priority

 Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 10/28/2002. It is noted, however, that applicant has not filed a certified copy of the Japan 2002-313076 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112 2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-7 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that the goal of the method and the final step do not agree. The claims are drawn to a method for determining a pigs resistance to an RNA virus. However, the claims recite the final step of detecting an 11 bp deletion in a swine Mx1 gene. The steps listed in the method do not result in the determination of whether or not a pig is resistance to an RNA virus. Therefore, it is unclear as to whether the claims are intended to be limited to a method for determining a pigs resistance to an RNA virus or a method of detecting an 11 bp deletion in a swine Mx1 gene

Claim Rejections - 35 USC § 112 1st paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance

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presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Nature of the Invention

The invention is drawn to a method for determining a pigs's resistance to an RNA virus. The claims comprise detecting an 11 bp deletion in a swine Mx1 gene exon, wherein the deletion is from positions 2064-2074 in the nucleotide sequence of SEQ ID NO: 1. The invention is in a class of inventions which the CAFC has characterized as 'the unpredictable arts such as chemistry and biology" (Mycolgen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)). The nature of the invention requires the knowledge of a reliable association between the presence and/or absence of the 11 bp deletion and any pigs resistance to any RNA virus.

Scope of the Claims:

In the instant case the claims are extremely broad for several reasons. The claims are drawn to a method for determining a pigs resistance to an RNA virus. Thus the claims encompass any breed of pig (i.e., Landrace, Middle Yorkshire, Large White, Berkshire, and Duroc). Additionally the claims encompass any RNA virus (i.e., influenza, vesicular stomatitis virus, PPRS). Also the claims are broad because they encompass detecting the 11 bp deletion at positions 2064-2074 of SEQ ID NO: 1, however they do not state whether it is the presence or absence of this deletion that is indicative of resistance to the RNA virus. Further the term "resistance" is broad because it encompasses complete and partial resistance.

Teachings in the Specification and Examples:

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The specification (page 3) teaches that in a previous study the inventors revealed that among domesticated pigs, some have an 11 bp deletion in the gene encoding the Mx1 protein, which is responsible for the suppression of myxovirus propagation. They further teach that the 11 bp deletion in the last exon of the Mx1 gene causes a frame shift of codons which relocates the stop codon to a much further position downstream and thus dramatically alters the downstream amino acid sequence. The resultant Mx1 protein has a different molecular weight and structure compared to the normal (wild type) protein, and has probably lost is ability to suppress virus propagation because of that.

The specification teaches (page 3) that the present inventors introduced a normal (wild type) Mx1 gene, a mutant Mx1 gene containing a 3 bp deletion in exon 13, a mutant Mx1 gene containing the 11 bp deletion in the last exon, or an empty vector into murine 3T3 cells which have no Mx1 activity and performed influenza A virus infection experiments. As shown in Fig 3 the 3 bp deletant had a virus propagation curve comparable to that of the wildtype and the deletion did not affect the virus suppression ability. However the 11 bp deletant completely lost its ability to suppress virus propagation and had a virus propagation comparable to that of the empty vector. It is further noted that while the 3 bp deletant and the wildtype were able to suppress the virus longer than the empty vector and 11 bp deletant, all of the these eventually were infected suggesting that the absence of the 11 bp deletant does not mean that the sample will be resistant to the virus it just means that it can suppress it longer.

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Example 1 describes cDNA cloning of normal and mutant Mx1 genes from Landrace pigs. Example 2 describes the construction of Mx1 gene expression vectors. Example 3 describes the preparation of Mx1 gene transformants. Example 4 describes the preparation of influenza virus particles. Example 5 describes the influenza virus infection experiments. Example 6 describes a comparison of Mx1 expression levels in the transformed cells. Example 7 describes the detection of an 11 bp deletion in the last exon of swine Mx1 gene by PCR amplification.

In the instant case the specification does not demonstrate that the 11 bp deletion occurs in any other breeds of swine. The teachings in the specification are limited to the Landrace breed. Further the specification does not demonstrate that Landrace pigs without the 11 bp deletion can suppress any type of RNA virus. The teachings in the specification are limited to influenza A virus. Further the absence of the 11 bp deletant does not appear to make the sample resistant to the virus it only appears to suppress the virus for a longer amount of time.

The Predictability or Unpredictability of the Art and Degree of Experimentation:

It is highly unpredictable as to whether the results obtained in Landrace pigs could be extrapolated to other breeds of pigs. The teachings in the specification contemplate applying this method to evaluating any pig's resistance to an RNA virus. However, results were obtained only using Landrace pigs. Knowledge that mutations in a gene occur in one breed (i.e. Landrace pigs) does not allow one to conclude that this gene and mutations in this gene will also occur in other breeds and will be associated with resistance to RNA viruses. The specification does not teach that the 11 bp deletion

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of the Mx1 gene occurs in a representative number of different breeds. The specification (page 1) only discloses that this deletion is present in Landrace and Duroc pigs and states that it has not been found in wild or half wild species. Accordingly, it is highly unpredictable as to whether the 11 bp deletion will occur in other breeds of pigs and if so it is unpredictable as to whether the deletion will be correlated with resistance to RNA viruses in other breeds of pigs.

Additionally it is highly unpredictable as to whether the results obtained with influenza A can extrapolated to any RNA virus. The prior art of Asano (J Vet Med Sci 2002) teaches that there was no difference in the effect on VSV infectivity between PK(15) type Mx1 and LLC-PK1 type Mx1 (here the PK (15) cells had the 11 bp deletion whereas the LLC-PK1 cells did not). Therefore Asano teaches that the difference of structure at the C terminal end of pig Mx1 protein did not influence the antiviral effect against VSV (page 1088). Therefore it is highly unpredictable whether the results obtained with influenza can be extrapolated to any RNA virus. Further Asano teaches that Mx proteins interfere with replication of various negative strand RNA viruses (page 1085). Based on this teaching it seems like only negative strand RNA viruses would be inhibited, yet the instant claims encompass any RNA virus.

Further it is unpredictable what can be concluded based on the Applicants experiments. While the Applicants have shown that the 3 bp deletant and the wildtype were able to suppress the virus longer than the empty vector and 11 bp deletant, all of the these eventually were infected suggesting that the absence of the 11 bp deletant does not mean that the sample will be resistant to the virus it just means that it can

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suppress it longer. Thus the absence of the 11 bp deletant does not appear to make the sample resistant to the virus it only appears to suppress the virus for a longer amount of time, yet the claims are drawn to a method for determining a pigs resistnace to an RNA virus.

Quantity of Experimentation:

The specification teaches an association between the presence of an 11 bp deletion in the Mx1 gene of a Landrace pig and reduced resistance to influenza A. To determine if this association can be used to determine ANY pig's resistance to ANY RNA virus would require extensive experimentation. For example, such experimentation may involve sequencing the Mx1 gene of different breeds of pigs and identifying which breeds the 11 bp deletion occurs in. Then after identifying breeds that have the deletion one would have to conduct viral infection assays with a variety of different RNA viruses to determine if the 11 bp deletion is associated with reduced resistance. Such random, trial by error experimentation is considered to be undue. The results of performing such methodology are highly unpredictable. The specification has provided only an invitation to experiment.

Conclusions:

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation." *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement

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provided by the specification to persons of ordinary skill in the art." The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v*Novo Nordisk 42 USPQ2d 1001 held that '(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the claims are not enabled because the specification only teaches that Landrace prigs have a decreased ability to suppress influenza A if the 11 bp deletion of the Mx1 gene is detected. However the claims encompass any pig and any RNA virus. The specification does not teach a representative number of additional swine breeds that have the 11 bp deletion of the Mx1 gene, wherein the presence of the deletion is indicative of decreased ability to suppress influenza A. Further the disclosure of a single RNA virus, influenza A is not representative of the broadly claimed genus of all RNA viruses. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art and the unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

As noted in the MPEP 211.02, "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." In the present situation, the process steps are able to stand alone and the preamble limitation is not accorded patentable weight. Accordingly, the claim language of "a method for determining a pigs resistance to an RNA virus" merely sets forth the purpose of the process, but does not limit the scope of the claims.

 Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Asano (J. Vet. Med. Sci 12/2002).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

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Regarding claim 1, Asano teaches that the coding region of the pig Mx1 gene was sequenced. Specifically Asano teaches that Mx1 cDNA derived from PK (15) cells had a deletion of 11 bp in the 3' end of the coding region (Page 1086). This 11 bp deletion is the same deletion that occurs at positions 2064-2074 of SEQ ID NO: 1. Thus Asano teaches a method that comprises the step of detecting an 11 bp deletion in a swine Mx1 gene exon, wherein the deletion is from positions 2064 to 2074 in the nucleotide sequence of SEQ ID NO: 1.

Regarding Claim 2, Asano teaches that the coding region of the pig Mx1 gene derived from PK (15) cells were amplified using a pair of primer. All of the PCR products were cloned and then confirmed by sequencing. Thus Asano teaches preparing a DNA sample from subject pig since at one time the cell lines came from a pig. Asano teaches amplifying the region of the Mx1 gene that comprises the 11 bp deletion, since Asano teaches that the whole coding region (nucleotides 29-2250) was amplified. Further Asano teaches determining the nucleotide sequence of the amplified DNA since Asano teaches a step of sequencing.

 Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Morozumi (Biochemical Genetics 8/2001).

Regarding claim 1, Morozumi teaches that they carried out PCR-RFLP on genomic DNA of 341 pigs from 15 different breeds. They found three different polymorphisms, one of which was an 11 bp deletion from positions 2064-2074 of the porcine Mx1 gene (pages 254 and 256 also Fig 1). Thus Morozumi teaches detecting

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an 11 bp deletion in a swine Mx1 gene exon, wherein the deletion is from positions 2064 to 2074 in the nucleotide sequence of SEQ ID NO: 1.

Regarding Claim 2, Morozumi teaches that genomic DNA was obtained from the pigs. Exon 14 was amplified using a forward and reverse primer and the amplified PCR fragments were sequenced on an ABI 3700 sequence (pages 253-254). Thus Asano teaches preparing a DNA sample from subject pig ,amplifying the region of the Mx1 gene that comprises the 11 bp deletion, since Morozumi teaches amplifying all of exon 14, and determining the nucleotide sequence of the amplified DNA.

Regarding Claim 3, Morozumi teaches that genomic DNA was obtained from the pigs. Exon 14 was amplified using a forward and reverse primer and the amplified PCR fragments were digested with the restriction endonucleases Narl and Nael. The digest PCR product were electrophoresed through 1.5% agarose gel, thereby separating the DNA fragments based on their size. Morozumi further teaches that the gel was photographed and shows a comparison of the sizes of detected DNA fragments (See Figs 2 and 3).

Regarding Claim 4, Morozumi teaches that genomic DNA was obtained from the pigs. Exon 14 was amplified using a forward and reverse primer and the amplified PCR fragments were digested with the restriction endonucleases Narl and Nael. The digest PCR product were electrophoresed through 1.5% agarose gel, thereby separating the DNA fragments based on their size. Morozumi further teaches that the gel was

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photographed and shows a comparison of the sizes of detected DNA fragments (See Figs 2 and 3).

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 3 and 4 rejected under 35 U.S.C. 103(a) as being unpatentable over
 Asano (J. Vet. Med. Sci 12/2002) in view of Morozumi (Biochemical Genetics 8/2001).
 The teachings of Asano are presented above.

Regarding Claim 3 Asano does not teach a method comprising preparing a DNA sample form a pig, digesting the sample with a restriction enzyme, separating the fragments based on size, and comparing the sizes of detected fragments. Regarding Claim 4 Asano does not teach a method comprising preparing a DNA sample form a pig, amplifying the region that comprises positions 2064-2074 of SEQ ID NO: 1, digesting the sample with a restriction enzyme, separating the fragments based on size, and comparing the sizes of detected fragments.

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However Morozumi teaches that genomic DNA was obtained from the pigs.

Exon 14 was amplified using a forward and reverse primer and the amplified PCR fragments were digested with the restriction endonucleases Narl and Nael. The digest PCR product were electrophoresed through 1.5% agarose gel, thereby separating the DNA fragments based on their size. Morozumi further teaches that the gel was photographed and shows a comparison of the sizes of detected DNA fragments (See Figs 2 and 3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention to substitute the deletion detection method of Asano for the deletion detection method of Morozumi because the substitution would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

 Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asano (J. Vet. Med. Sci 12/2002) in view of Singh (US Patent 6322980 2001).

The teachings of Asano are presented above.

Regarding Claim 5 Asano does not teach a method comprising preparing a DNA sample form a pig, amplifying the region that comprises positions 2064-2074 of SEQ ID NO: 1, dissociating the amplified DNA into single strands, separating the single stranded DNAs on a non denaturing gel and comparing the gel mobility of the fractionated single stranded DNAs. Regarding Claim 6 Asano does not teach a method of preparing a DNA sample from a pig, amplifying the region that comprises positions 2064-2074 of SEQ ID NO: 1, determining the molecular weight of the DNA amplified using mass spectrometry and comparing the molecular weight. Regarding Claim 7

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Asano does not teach a method of preparing a DNA sample from a pig, amplifying the region that comprises positions 2064-2074 of SEQ ID NO: 1, preparing a substrate with an immobilizes probe, contacting the DNA with the substrate, determining the intensity of hybridization.

However Singh discloses multiple methods for detecting the presence of nucleic acid variants. For example Singh discloses SSCP which comprises all of the steps required by claim 5, sizing by mass spectroscopy which comprises all of the steps required by claim 6, and high density array hybridization which comprises all of the steps required by claim 7.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention to substitute the deletion detection method of Asano for any of the deletion detection methods of Singh because the substitution would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Morozumi (Biochemical Genetics 8/2001) in view of Singh (US Patent 6322980 2001).

The teachings of Morozumi are presented above.

Regarding Claim 5 Morozumi does not teach a method comprising preparing a DNA sample form a pig, amplifying the region that comprises positions 2064-2074 of SEQ ID NO: 1, dissociating the amplified DNA into single strands, separating the single stranded DNAs on a non denaturing gel and comparing the gel mobility of the fractionated single stranded DNAs. Regarding Claim 6 Morozumi does not teach a

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method of preparing a DNA sample from a pig, amplifying the region that comprises positions 2064-2074 of SEQ ID NO: 1, determining the molecular weight of the DNA amplified using mass spectrometry and comparing the molecular weight. Regarding Claim 7 Morozumi does not teach a method of preparing a DNA sample from a pig, amplifying the region that comprises positions 2064-2074 of SEQ ID NO: 1, preparing a substrate with an immobilizes probe, contacting the DNA with the substrate, determining the intensity of hybridization.

However Singh discloses multiple methods for detecting the presence of nucleic acid variants. For example Singh discloses SSCP which comprises all of the steps required by claim 5, sizing by mass spectroscopy which comprises all of the steps required by claim 6, and high density array hybridization which comprises all of the steps required by claim 7.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention to substitute the deletion detection method of Morozumi for any of the deletion detection methods of Singh because the substitution would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

12. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SHAW whose telephone number is (571)272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to

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reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw Examiner Art Unit 1634

/Juliet C Switzer/

Primary Examiner, Art Unit 1634